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DISCUSSION PAPER ON ALLERGEN LABELLING

(Prepared by Australia, the United Kingdom and the United States of America)

1. INTRODUCTION

The *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985) (GSLPF) includes provisions for the declaration of certain foods and ingredients known to cause hypersensitivity (referred to as 'allergen labelling' in this paper).

In the context of the future work and direction for the Codex Committee on Food Labelling (CCFL), it was agreed at the 44th session of CCFL (REP18/FL, para 58) in October 2017 to develop discussion papers on:

- a. Internet sales/e-commerce;
- b. Allergen labelling;
- c. Innovation – use of technology in food labelling;
- d. Alcoholic beverages labelling;
- e. Criteria for the definition of 'high in' nutritional descriptors for fats, sugars and sodium; and
- f. Labelling of food in joint presentation and multipack formats.

It was also agreed information would be sought through a Circular Letter on current practices, issues and any potential role in the areas identified, or in the case of alcoholic beverages labelling and allergen labelling where some Codex provisions already exist, any potential further role for CCFL (REP18/FL, para 59).

A Circular Letter (CL 2018/24-FL) with an annex for each topic was distributed in April 2018. Annex 2 sought information specific to allergen labelling and a total of 22 responses were received (18 Codex Members, 1 Codex Member Organisation and 3 Codex Observers).

This discussion paper summarises the information received in these responses, identifies issues about the allergen labelling provisions in the GSLPF and related texts, and recommends areas of further work for CCFL.

2. BACKGROUND

2.1 Public health significance of food hypersensitivity

Most consumers enjoy food without a problem or risk to their health, however a proportion of people can experience adverse reactions during or following the consumption of specific foods. These people may have a food allergy (involving the immune system), a food intolerance (not involving the immune system) or coeliac disease (an autoimmune disease caused by a reaction to gluten).

Allergies to food can be classified by their immune mechanism:

- immunoglobulin E (IgE)-mediated (immediate hypersensitivity),
- non-IgE mediated (cell-mediated, or delayed hypersensitivity), and
- mixed IgE and non-IgE mediated.

IgE-mediated symptoms typically develop within minutes to 1-2 hours of ingesting the food. Non-IgE-mediated and mixed IgE- and non-IgE-mediated food allergies present with their symptoms several hours after the ingestion of the food.

Symptoms of IgE-mediated food allergy may include itching around the mouth, hives, swelling of lips and eyes, breathing difficulties, a drop in blood pressure, diarrhoea, anaphylaxis, and may result in death.

Coeliac disease is a serious lifelong illness where the body's immune system attacks its own tissues when gluten proteins are consumed. This causes damage to the lining of the gut and an inability of the body to properly absorb nutrients from food.

Food intolerances are often reactions to non-protein substances in foods. An intolerance reaction is usually delayed, with no observable effect for several hours after eating the food. Symptoms are similar to those of allergy, although often less severe, and can include: hives, eczema and other itchy skin rashes; stuffy or runny nose; asthma; frequent colds or ear infections; mouth ulcers; reflux; bloating; stomach aches, constipation and/or diarrhoea and incontinence; migraines or headaches; lack of concentration; anxiety; depression; lethargy; irritability; and sleeping difficulties.

Allergen labelling is intended to provide consumers with access to clear and accurate information on the presence of allergens (or substances) in foods, so that they can make safe and informed food choices. This is particularly significant given the potential life-threatening consequences for food allergic individuals, and that the prevalence of food allergies is increasing in many parts of the world^{1,2}.

This increased prevalence of food allergy is occurring primarily in Western countries, such as the United Kingdom (and other countries across Europe), the United States and Australia². Elsewhere, there is a lack of food allergy prevalence data particularly for developing nations, however the data that exists indicates these countries are also experiencing an increase in the prevalence of food allergies and food allergy sensitisation. Most of these data have come from Asia (China) and Africa, although there are reports that the prevalence of food allergy is also increasing in Latin American nations^{3,4}.

2.2 Relevant Codex labelling texts

2.2.1 General Standard for the Labelling of Prepackaged Food

Section 4 (*Mandatory Labelling of Prepackaged Foods*) of the GSLPF includes a provision for the declaration of eight foods and ingredients that have been identified as causing hypersensitivity on a global scale (section 4.2.1.4).

There are also several other sections in the GSLPF that contain provisions relevant to the declaration of these foods and ingredients. All relevant sections are provided in the box below.

¹ Boyce J, Assa'ad. A, Burks A, Jones S, Sampson H, Wood R, Plaut M, Cooper S and Fenton M (2010). Guidelines for the Diagnosis and Management of Food Allergy in the United States: Report of the NIAID-Sponsored Expert Panel. *Journal of Allergy and Clinical Immunology*, 126(6):1-58. doi: 10.1016/j.jaci.2010.10.007

² Tang ML, Mullins SJ (2017). Food Allergy: Is prevalence increasing? *Internal Medicine Journal*, 47(3):256-261. doi: 10.1111/imj.13362.

³ Hu Y, Chen J, Li H (2010). Comparison of food allergy prevalence among Chinese infants in Chongqing, 2009 versus 1999. *Pediatrics International*, 52(5):820-824. doi: 10.1111/j.1442-200X.2010.03166.x

⁴ Leung AS, Wong GW, Tang LK (2018). Food Allergy in the developing world. *Journal of Allergy and Clinical Immunology*, 141(1):76-78. doi: 10.1016/j.jaci.2017.11.008.

Extracted text from the *General Standard for the Labelling of Prepackaged Foods (CXS 1-1985)* relevant to allergen labelling

3. GENERAL PRINCIPLES

3.1 Prepackaged food shall not be described or presented on any label or in any labelling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect.¹

1. Examples of descriptions or presentations to which these General Principles refer are given in the Codex *General Guidelines on Claims*.

4.2 LIST OF INGREDIENTS

4.2.1.3 Where an ingredient is itself the product of two or more ingredients, such a compound ingredient may be declared, as such, in the list of ingredients, provided that it is immediately accompanied by a list, in brackets, of its ingredients in descending order of proportion (m/m). Where a compound ingredient (for which a name has been established in a Codex standard or in national legislation) constitutes less than 5% of the food, the ingredients, other than food additives which serve a technological function in the finished product, need not be declared.

4.2.1.4 The following foods and ingredients are known to cause hypersensitivity and shall always be declared:²

- Cereals containing gluten; i.e., wheat, rye, barley, oats, spelt or their hybridized strains and products of these;
- Crustacea and products of these;
- Eggs and egg products;
- Fish and fish products;
- Peanuts, soybeans and products of these;
- Milk and milk products (lactose included);
- Tree nuts and nut products; and
- Sulphite in concentrations of 10 mg/kg or more.

² Future additions to and/or deletions from this list will be considered by the Codex Committee on Food Labelling taking into account the advice provided by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

4.2.2 The presence in any food or food ingredients obtained through biotechnology of an allergen transferred from any of the products listed in Section 4.2.1.4 shall be declared. When it is not possible to provide adequate information on the presence of an allergen through labelling, the food containing the allergen should not be marketed.

4.2.3 A specific name shall be used for ingredients in the list of ingredients in accordance with the provisions set out in Section 4.1 (Name of the Food) except that:

4.2.3.1 Except for those ingredients listed in section 4.2.1.4, and unless a general class name would be more informative, the following class names may be used:

(Note only class names relevant to Section 4.2.1.4 are provided below)

Name of Classes	Class Name
Refined oils other than olive	'Oil' together with either the term 'vegetable' or 'animal', qualified by the term 'hydrogenated' or 'partially-hydrogenated', as appropriate
Refined fats	'Fat' together with either, the term 'vegetable' or 'animal', as appropriate.
Starches, other than chemically modified starches	'Starch'
All species of fish where the fish constitutes an ingredient of another food and provided that the labelling and presentation of such food does not refer to a specific species of fish.	'Fish'
All types of cheese where the cheese or mixture of cheeses constitutes an ingredient of another food and provided that the labelling and presentation of such food does not refer to a specific type of cheese.	'Cheese'
All types of caseinates.	'Caseinates'
Milk products containing a minimum of 50% of milk protein (m/m) in dry matter	'Milk Protein'

4.2.4 Processing aids and carry-over of food additives

4.2.4.1 A food additive carried over into a food in a significant quantity or in an amount sufficient to perform a technological function in that food as a result of the use of raw materials or other ingredients in which the additive was used shall be included in the list of ingredients.

4.2.4.2 A food additive carried over into foods at a level less than that required to achieve a technological function, and processing aids, are exempted from declaration in the list of ingredients. The exemption does not apply to food additives and processing aids listed in section 4.2.1.4.

6. EXEMPTIONS FROM MANDATORY LABELLING REQUIREMENTS

With the exception of spices and herbs, small units, where the largest surface area is less than 10 cm², may be exempted from the requirements of paragraphs 4.2 and 4.6 to 4.8.

8. PRESENTATION OF MANDATORY INFORMATION

8.1 General

8.1.1 Labels in prepackaged foods shall be applied in such a manner that they will not become separated from the container.

8.1.2 Statements required to appear on the label by virtue of this standard or any other Codex standards shall be clear, prominent, indelible and readily legible by the consumer under normal conditions of purchase and use.

8.1.3 Where the container is covered by a wrapper, the wrapper shall carry the necessary information or the label on the container shall be readily legible through the outer wrapper or not obscured by it.

8.2 Language

8.2.1 If the language on the original label is not acceptable, to the consumer for whom it is intended, a supplementary label containing the mandatory information in the required language may be used instead of relabelling

8.2.2 In the case of either relabelling or a supplementary label the mandatory information provided shall be fully and accurately reflect that in the original label.

2.2.2 Previous amendments to allergen labelling provisions

Since the GSLPF was adopted in 1985, the provisions relating to allergen labelling have been amended on three occasions as detailed in the table below.

Year	Amendment(s)
1999	Inclusion of a list of food and ingredients known to cause hypersensitivity (section 4.2.1.4) and lowering the 25% rule to 5% rule for compound ingredients (section 4.2.1.3)
2001	Insertion of a new paragraph relating to biotechnology (section 4.2.2)
2003	Insertion of 'Milk Protein' in the list of class names (section 4.2.3.1)

2.3 Codex Committee on Food Hygiene

The Codex Committee on Food Hygiene (CCFH) is developing a code of practice (CoP) to provide guidance to food business operators and competent authorities on managing allergens in food production, including controls to prevent cross-contact. The scope of the CoP is allergen management throughout the supply chain including primary production, during manufacturing, and at retail and food service endpoints. The CoP is intended to complement the GSLPF and support industry compliance.

At the 50th session of CCFH in November 2018, CCFH agreed to forward the proposed draft *Code Of Practice on Food Allergen Management for Food Business Operators* to the Codex Alimentarius Commission (CAC) for adoption at Step 5 (REP19/FH, paras 48 – 56 and Appendix III)⁵.

Of particular relevance to CCFL is that the proposed draft CoP includes definitions for 'allergen' (which does not capture sulphites), 'allergen profile' and 'precautionary allergen labelling' and recognises the use of scientifically based threshold levels and precautionary allergen labelling as tools to manage risks for consumers. The CCFH agreed to submit the food labelling provisions to CCFL for endorsement (Paras. 158 and 159 of Appendix III) and to also seek advice from CCFL on:

- a. the appropriateness of the use of a precautionary allergy labelling statement (Paras. 14, 72, 152, 160, 161 of Appendix III) and the related definition (Para. 28 of Appendix III);
- b. the list of foods which cause allergenic reactions (Para. 9 of Appendix III).

Further, CCFH agreed to request FAO/WHO convene an expert consultation to provide scientific advice⁶ and to inform CCFL of this request (REP19/FH, para 56).

2.4 Other guidance

Information provided in responses to Annex 2 indicated guidance relating to food allergen management and labelling is also available to assist food industry. While some of this guidance material is provided by government (or example, Swedish *Food Sector Guidelines for management and labelling of food products with reference to allergy and other intolerance*), other guidance is produced by industry organisations (for example, guidance by on good fining practices for wine using agents with allergenic potential such as egg, fish and milk⁷).

Guidance on food allergen management and the use of precautionary allergen or advisory labelling to indicate the unintentional presence of allergens is available in some countries. Such guidance either focusses on labelling recommendations or requirements, or includes risk assessment tools for use by food industry to determine whether allergenic protein is present as a result of cross-contact and thereby presents a risk to consumers.

In addition to industry guidance, some Codex Members' responses stated they provide food allergen information intended for a broader audience including consumers.

⁵ Draft *Code of Practice on Food Allergen Management for Food Business Operators* accessible from the Report of CCFH50 meeting, at: <http://www.fao.org/fao-who-codexalimentarius/meetings/detail/en/?meeting=CCFH&session=50>

⁶ The Terms of Reference for FAO/WHO expert consultation on risk assessment of food allergens are included in paragraph 56, REP19/FH.

⁷<https://www.fivs.org/virtuallibrary/link/id/27993/challenge/1421465469/hash/995693dc87a5552bd6c2d664f04a88819d748602/>

3. ISSUES

3.1 Scope

The GSLPF applies to the labelling of all prepackaged foods to be offered as such to the consumer or for catering purposes. Section 2 of the GSLPF includes definitions for 'prepackaged'⁸ and 'foods for catering purposes'⁹. However the scope of the standard as it applies to food for catering purposes may not be clear, for example where the caterer prepacks the food for direct sale to consumers. There is also the issue of the provision of allergen information applying to internet sales of food. The issue of internet sales /e-commerce is a separate topic for discussion under agenda item 7 (CX/FL 19/45/7).

Some Codex Members indicated their national/regional ingredient declaration requirements apply more broadly, for example European food information rules require allergen ingredient information to be made available for all foods (prepacked and non-prepacked).

3.2 Definitions

Section 4.2.1.4 of the GSLPF specifies 'the following foods and ingredients are known to cause hypersensitivity...', however 'hypersensitivity' is not defined. This is significant in that the current list of foods and ingredients can produce a range of adverse health effects, which vary in their severity.

From the comments received there were differing views about the use of 'hypersensitivity'. While some responses supported its use, others viewed it as inappropriate and not readily understood to pertain to food allergy. There were also suggestions for alternate terms such as 'food allergy', 'food allergen', and 'sensitizers' to be defined.

There was however general consensus amongst responses for the GSLPF to include a definition for 'hypersensitivity' or an alternative term(s) to clarify which adverse reactions are within scope (for example, allergic reactions, Coeliac disease, and/or intolerances), and to allow for any future modifications to the list of foods and ingredients in Section 4.2.1.4.

3.3 List of foods and ingredients to be declared

In general, comments indicated that CCFL should consider revising Section 4.2.1.4 of the GSLPF, noting a need for greater harmonisation of allergen labelling standards at an international level. This specifically related to differing national/regional standards for allergen labelling, which when compared to the GSLPF, either omit or include additional foods or ingredients that must be declared. The potential negative impacts on trade from this lack of harmonisation were noted in some responses. A comparison of the different allergen declarations required internationally has been compiled by the Food Allergy Research and Resource Program (FARRP) at University of Nebraska¹⁰.

Comments received also raised more specific issues with the existing text in Section 4.2.1.4. In most cases, the need for improved clarity in the text was raised as discussed below.

3.3.1 Grouping of foods

Concern about the grouping of foods (i.e. 'tree nuts', 'cereals that contain gluten', etc.) was raised in multiple responses. Some stated it is unclear which specific foods are included in each of these groups. Concern was also expressed that international variability in the foods included in these groupings can have trade implications.

Cereals containing gluten; i.e., wheat, rye, barley, oats, spelt or their hybridized strains and products of these

There were several comments stating that a distinction is needed to be made between an allergenic reaction to wheat and a gluten intolerance under "gluten containing cereals". Some Codex Members noted they may make labelling distinctions based on the type of hypersensitivity (i.e. listing allergens and declaring the presence of gluten). Clarity was requested about the statement, "and products of these" because this statement is not defined. (Note: this statement is also used elsewhere in the text).

Tree nuts and nut products

Comments stated that the GSLPF could make it clear which particular tree nuts must be declared by having a specific list. Comments stated there is variation across national/regional legislation in which foods are considered to be "nuts". Some responses provided a list of which foods they believe should be included in this

⁸ 'Prepackaged' means packaged or made up in advance in a container, ready for offer to the consumer, or for catering purposes.

⁹ 'Foods for Catering Purposes' means those foods for use in restaurants, canteens, schools, hospitals and similar institutions where food is offered for immediate consumption.

¹⁰ Food Allergy Research and Resource Program (FARRP) (2018). Food allergy – international regulatory chart. Available at: <https://farrp.unl.edu/IRChart>.

grouping. One comment stated that foods listed within the "tree nut" grouping should be listed by both their common name and their scientific specification taxonomy.

Fish and fish products

Several responses indicated a need for clarity due to uncertainty about whether molluscs should be listed. They stated consumers and health professionals may refer to 'shellfish' allergy – however in some jurisdictions, molluscs may be included in the definition of 'fish'. This causes confusion for consumers and food producers alike, and is also a safety issue for those with allergy to seafood such as abalone, calamari, clams, mussels, oysters, scallops, squid etc.

Peanuts, soybeans and products of these

There was agreement among comments that peanuts and soybeans should be listed separately even though they were both legumes.

Milk and milk products (lactose included)

One comment requested that the definition of "milk" be clarified with regards to the species; if it applies to cow's milk only or also includes other mammalian milk (goat, sheep etc.). Additionally, the point was raised over potential confusion in allergen labelling due to the use of the term "milk" in relation to non-animal sourced products.

Sulphite in concentrations of 10 mg/kg or more

One comment stated that there could be some additional clarification in this area because some Codex Members express sulphite as SO₂ or SO₃ with the same threshold of 10mg/kg.

3.3.2 Additions and exemptions

Some responses commented that CCFL should consider whether the current list of foods and ingredients to be declared should be expanded for consumer protection and to facilitate trade. A variety of approaches to identify new foods or ingredients which may cause hypersensitivity and should be declared were raised. Suggested inclusions were sesame seed, lupin, molluscs, celery, mustard and several food colours. However others commented that there are no additional foods/ingredients they believe should be added to the current list. One Codex Member suggested Codex develop a list of ingredient exemptions from allergen labelling for inclusion in the GSLPF.

3.3.3 Criteria for addition or deletion

There were comments that there is a need for clear rules on making new exemptions or inclusions in the list of substances that cause hypersensitivity.

A footnote to section 4.2.1.4 states, "Future additions to and/or deletions from this list will be considered by the Codex Committee on Food Labelling taking into account the advice provided by the Joint FAO/WHO Expert Committee on Food Additives (JECFA)." Previous CAC reports from 1997 and 1999 refer to this footnote^{11,12}. In the 1997 report (ALINORM 97/37, paras 119 – 121) the CAC noted CCFL had requested further scientific advice in order to determine which foods should be included in the list and the criteria to do so. The then WHO Secretary of JECFA agreed in principle that it would be possible to address this issue in the framework of JECFA. In 1999, following advice received from JECFA (53rd Report of JECFA, Annex 4)¹³, who had established an ad hoc Panel on Food Allergens to consider the criteria for the inclusion of foods and food ingredients in the list, CAC adopted the list with the addition of the footnote at Step 8 (ALINORM 99/37, para 134).

For some ingredients derived from or containing allergens, their processing or composition means that they may pose a low risk of causing a hypersensitivity reaction. In the GSLPF there are no exemptions from declaring these types of ingredients. However, some Codex Members indicated that they do provide exemptions and others indicated that they are currently considering approaches to exemptions.

¹¹ CAC22 Report, 1997. Available online: http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-701-22%252Fai97_37e.pdf

¹² CAC23 Report, 1999. Available online: http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-701-23%252Fai99_37e.pdf

¹³ WHO Technical Report Series 896 (2000). Report of an ad hoc Panel on Food Allergens. Annex 4 of Evaluation of certain food additives and contaminants. Fifty-third report of the Joint FAO/WHO Expert Committee on Food Additives. <https://www.who.int/foodsafety/publications/jecfa-reports/en/>.

Of those Codex Members which indicated they have systems in place for labelling exemptions, three general types of approaches were described for how these exemptions are set, being:

- a. the use of risk assessments by national government agencies
- b. reliance on allergen protein levels for exemption
- c. the allergen is already mentioned in the name of the food.

3.4 Compound ingredients

Some responses expressed the view that section 4.2.1.3 of the GSLPF could be clarified to ensure foods and ingredients listed in section 4.2.1.4 (that are not food additives that serve a technological function in the finished product) must be declared when present as ingredients of a compound ingredient in amounts of less than 5% of the food (for example, wheat flour).

Although section 4.2.4.2 specifies that food additives and processing aids listed in 4.2.1.4 are not exempt from the requirement to be declared in the list of ingredients, there appears to be a gap for allergenic ingredients that are neither food additives nor processing aids.

3.5 Consumer issues

3.5.1 Identifying and understanding allergen information

When shopping for food, it takes more organisation and time for an individual with an allergy. This is because there is a need to review the ingredient information to ensure the food they purchase is suitable and safe. Having all allergen information presented in one place such as in the ingredient list and / or using shortcuts, such as “contains” statements which list the allergens or “free from” claims, have been found to make food shopping easier.

Food innovation has also resulted in a diversity of food ingredients and food composites which can make it difficult for the consumer to understand the true provenance / nature of the ingredient. For example, the components and forms of milk products can be diverse (for example, butter, whey, casein, lactose, skimmed milk powder, milk protein, cheese, cream).

A number of Codex Members reported that they have introduced their own legislation that require food labels to present information as simply as possible. Regulatory approaches include referencing the specific allergen source and requiring these terms to be declared on food labels. For example, requirements to ensure that casein should be easily distinguishable from other ingredients such as “milk casein” or “casein (milk)” within the ingredient list.

There were also comments that consumers should be able to rely on allergen declarations being understandable and using terms that are familiar. Other comments referred to the need to use consistent terminology to declare allergens on labels. It was noted that the current text in the GSLPF can allow allergen declarations to be vague, inaccurate, or too technical in nature.

There was a general view that clarification of the GSLPF would lead to improved consumer understanding as a result of clearer and more consistent allergen labelling.

3.5.2. Presentation and legibility

Responses noted the GLSPF does not specify the placement of allergen information in a specific location on a food label, or even within the ingredient list itself. In addition, the GLSPF does not indicate how information should be presented in a manner that clarifies the nature of the ingredients. There is also nothing in the standard about co-locating allergen information in the same area or field of vision. In relation to the legibility of allergen information, the GSLPF does not specify a minimum font size, although it does state the information shall be clear, prominent, indelible and readily legible by the consumer under normal conditions of purchase and use (Section 8.1.2).

The lack of specifications on the location of allergen declarations means that vital information could be missed. Providing allergen information in different formats (for example, an ingredient list and a “contains” statement) there is a risk information could be missing or presented in an inconsistent manner on the same food label, unless some additional controls are in place.

A number of Codex Members indicated that they have national/regional requirements for the use of highlighting or specific fonts when allergens are declared on a label e.g. bolding of text. These requirements were noted with views expressed that allergen information should be clearly visible on a food label, and easily identifiable from surrounding text. Some Codex Members indicated that allergen declarations should be bolded so that they are displayed more prominently. The language used in the country that the product is marketed in, and the use of warnings on labels were also issues raised.

3.6 Precautionary allergen or advisory labelling

Precautionary allergen or advisory labelling is used to provide information about the unintentional presence of allergens due to cross-contact during storage, transport and manufacturing of a food product. For example:

- a. *May contain...*
- b. *May be present...*
- c. *May contain traces of...*
- d. *Not suitable for...*
- e. *Made on a line which also handles...*
- f. *Made in a factory which also handles...*

When determining the use of a precautionary/advisory statement, a decision point on the risk from the allergen's presence is required. However, there is currently no international agreement on the exposure of allergen (called the reference dose or 'action level') that is considered "safe" for the allergic consumer. Therefore, there is variability in how risk from the unintentional presence of allergens is managed through labelling, which has the potential to create trade barriers where action levels are lower in the importing country. The European Food Safety Authority (EFSA) is currently in the process of organising original research into action levels for allergens, however this work and its outcomes will likely take several years.

Some Codex Members have already implemented action levels for the use of precautionary allergen or advisory labelling statements. In Japan, the approach is to have a default 10ppm action level for allergen cross-contamination. In Switzerland, the labelling for the unintentional presence of allergens is required at >1000ppm. In both countries, their legislation requires the allergen to be declared as an ingredient if they exceed these levels.

Some Codex Members regulate the use of precautionary allergen or advisory labelling statements, while others allow the voluntary use of precautionary allergen or advisory labelling but require specific wording (for example, 'may contain...') when used. There are also Codex Members that require a specific precautionary allergen or advisory labelling statement when there is the risk of allergen cross-contact, but do not set any thresholds in their legislation.

In other countries/regions, there are no regulatory measures relating to the use of precautionary allergen or advisory labelling, but there are voluntary systems in place to control their use. One example is the Voluntary Incidental Trace Allergen Labelling (VITAL®) Program¹⁴, which uses population level data to derive reference doses to inform 'action levels' for foods. The VITAL® Program also provides guidance to food manufacturers about the use of the statement 'may be present...' on food labels and in what circumstances it should be used. VITAL® was originally produced for the Australian food industry, however it is being adopted elsewhere.

The Belgian and Dutch food authorities have also utilised the VITAL clinical database as a means of developing scientific opinions on reference doses to inform action levels. However, these reference doses differ from those set in Australia and New Zealand as they are based on different scientific opinions regarding appropriate risk management for their populations.

None of the approaches mentioned above have received international agreement for use. Therefore, inconsistency on how food allergen risk from cross-contact is managed and communicated on food labels remains. Comments indicated that because of this global variability, there is a need for the GSLPF to contain some type of specification for precautionary allergen or advisory labelling statements. The majority of these comments called for standardisation of the wording used for precautionary allergen or advisory labelling statements, although there were also requests for the GSLPF to contain some risk-based guidance for when these statements can be displayed.

3.7 'Free from' labelling

The only defined Codex limit for 'free from' foods is that used for gluten free claims. The *Standard for foods for special dietary use for persons intolerant to gluten* (CXS 118-1979) defines gluten-free foods as those with a gluten level not exceeding 20 mg/kg in total. However the approach for the labelling of gluten-free appears to vary in its application. Within EU¹⁵, US¹⁶ and Canadian regulations the provision of information to consumers

¹⁴ The VITAL ® Program provides a risk-based methodology for food producers to use in assessing the impact of allergen cross-contact. Available at: <http://allergenbureau.net/vital/>

¹⁵ EU Commission implementing Regulation 828/2014 for the provision of information to consumers on the absence or reduced presence of gluten in food. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0828&from=EN>.

¹⁶ Note in the U.S that in addition to the 20 ppm limit, the food must *not* contain: an ingredient that is any type of wheat, rye, barley, or crossbreeds of these grains; an ingredient derived from these grains that has *not* been processed to remove

on the absence of gluten in foods states that a limit of <20 mg/kg applies for 'gluten-free'. In Australia and New Zealand 'gluten free' foods must not have any detectable levels of gluten¹⁷.

Other 'free from' claims (such as milk free, wheat free, egg free) are generally dealt with through the *General Guidelines on Claims* (CXG 1-1979). Section 5.1 of these guidelines specifies conditions for claims that highlight the absence or non-addition of particular substances to food. In some countries/regions there is also industry guidance available to help inform industry approaches¹⁸. The general approach is that products with free from claims should not have any detectable allergen present, rather than the use of clinical data to define level of protection offered to the allergic population.

This is further complicated by inconsistent criteria for allergen testing, validation and verification of such claims, which can lead to variation in what is defined as "free from". Finally, as innovation in analytical technology improves, the definition of what is "absent" or "free-from" shifts as analytical methods increase their level of sensitivity to detect allergens in food.

Comments received mentioned 'free' claims for allergens should be based on no detectable limits, given the serious health effects associated with allergies. However, the comments made no reference to 'gluten-free' claims in this context.

4. CONCLUSION

Despite some amendments to the GSLPF since section 4.2.1.4 was included in 1999, there have been no substantive changes to the provisions relating to the declaration of foods and ingredients known to cause hypersensitivity. However, from the responses received there is support for work to develop definitions, clarify the listed foods and ingredients, and potentially update the current list to include new foods and ingredients or provide exemptions. The GSLPF is also viewed as lacking sufficient detail in how allergens should be presented on food labels to ensure consumer protection and to provide more technical specification for industry. This view recognises that since the inclusion of allergen labelling provisions in the GSLPF there has been an increase in food innovation leading to more complex food manufacturing processes and variations in industry labelling practices, including the use of precautionary allergen or advisory labelling and 'free from' claims. This has led to allergen labelling that is not always clear or understood by consumers, who rely on labelling information to make safe food choices.

Also noting the recent work by CCFH on a CoP and proposal to request FAO/WHO convene an expert consultation to provide scientific advice regarding threshold levels (refer to section 2.3), it is timely for CCFL to consider whether guidance on for precautionary allergen or advisory labelling is needed.

5. RECOMMENDATION TO CCFL

From the issues identified there appears a need to review and clarify allergen labelling provisions in the GSLPF (and related texts if required), including consideration of precautionary allergen or advisory labelling. This is particularly with the view to improve clarity and ensure clear and consistent information for consumers, and to increase harmonization to facilitate trade.

It is therefore recommended CCFL initiate new work to review the provisions for the declaration of foods and ingredients known to cause hypersensitivity (allergen labelling) and submit the attached Project Document (Appendix 1) to CAC for approval.

The work to address the identified issues is proposed to be undertaken in three areas as follows:

- 1) Review provisions relevant to allergen labelling in the GSLPF (and related texts as required) to consider:
 - a) Scope and definitions
 - b) Presentation, legibility and the terms to be used when making declarations and how and where the information is presented on the label
 - c) The suitability of class names in relation to section 4.2.1.4
 - d) Clarification of the application of compound ingredient labelling provisions (section 4.2.1.3) to allergen declarations
 - e) Subject to expert advice (as per Part 3),

gluten, or, an ingredient derived from these grains that *has* been processed to remove gluten, but results in the food containing more than 20 ppm of gluten.

¹⁷ Australia New Zealand Food Standards Code, Standard 1.2.7 Nutrition, health and related claims and Schedule S3 —4 Nutrition, health and related claims <http://www.foodstandards.gov.au/code/Pages/default.aspx>.

¹⁸ Food Drink Federation Guidance on "free from" allergen claims https://www.fdf.org.uk/corporate_pubs/brc-free-from-guidance.pdf.

- i) Changes to the list in section 4.2.1.4 (i.e. additions, deletions or exemptions)
 - ii) Clarity of the groupings of foods/ingredients in section 4.2.1.4.
- 2) Develop guidance on the use of precautionary allergen or advisory labelling including:
- a) Principles for the use of precautionary allergen or advisory labelling
 - b) Labelling provisions, including definition(s) for precautionary allergen or advisory labelling
 - c) The location and appropriate Codex text(s) for the guidance.
- 3) Request scientific advice relating to the list of foods and ingredients in section 4.2.1.4 from FAO/WHO on:
- a) Whether the published criteria¹⁹ for assessing additions and exclusions to the list in section 4.2.1.4 is still current and appropriate.
 - b) Subject to the advice on the criteria above
 - i) whether there are new foods and ingredients that should be added to the list.
 - ii) clarification of the foods and ingredients in the list in section 4.2.1.4 including
 - (1) whether fish includes molluscs?
 - (2) which specific tree nuts are associated with food allergy?
 - (3) whether mammalian milk that is not cow's milk must be declared?
 - iii) Whether there is sufficient evidence for certain highly refined foods and ingredients to be exempted from the list.

Noting there were also issues identified in relation to 'free from' labelling which are broader i.e. relate to Codex texts other than the GSLPF, it is recommended this issue be considered separately and is therefore not included in the current work proposal. CCFL may wish to further consider whether separate new work should be undertaken in the future on:

- Reviewing the adequacy of existing Codex texts to characterise the technical issues for defining 'free'.
- The need to develop criteria for 'free from' allergen labelling, such as 'wheat free' or 'dairy free'.

¹⁹ WHO Technical Report Series 896 (2000). Report of an ad hoc Panel on Food Allergens. Annex 4 of Evaluation of certain food additives and contaminants. Fifty-third report of the Joint FAO/WHO Expert Committee on Food Additives. <https://www.who.int/foodsafety/publications/jecfa-reports/en/>.

APPENDIX 1

PROJECT DOCUMENT

1. PURPOSE AND SCOPE OF THE NEW WORK

Declaration of foods or ingredients known to cause hypersensitivity (referred to as allergen labelling) is intended to provide consumers with access to clear and accurate information on the presence of allergens (or substances) in foods, so that they can make safe food choices. This is particularly significant given the potential life-threatening consequences for food allergic individuals, and that the prevalence of conditions is increasing in many parts of the world.

This project proposes to review and clarify the provisions relevant to allergen labelling in the *General Standard for Labelling of Pre-packaged Foods* (CXS 1-1985) (the *Standard*), and to develop guidance on precautionary allergen or advisory labelling, to provide clear and consistent allergen information for consumers, and increase harmonization to facilitate trade. This proposal does not seek to revise the whole of the *Standard*.

2. RELEVANCE AND TIMELINESS

Globally the prevalence of food allergies is increasing, including in developing countries. Given the serious nature of food allergies and its health consequences, and the increasing complexity of the food supply chain, the current allergen labelling provisions in the *Standard* are considered to lack sufficient clarity and detail for industry in how allergens should be presented on food labels to ensure consumer protection. There is also global variation in national/regional standards for allergen labelling which impacts on harmonization and trade.

This work complements the recent work by the Codex Committee on Food Hygiene (CCFH) on a draft *Code of Practice on Food Allergen Management for Food Business Operators* at Step 5 (REP19/FH, paras 48 – 56 and Appendix III), and the proposal by CCFH to request FAO/WHO convene an expert consultation to provide scientific advice regarding allergen threshold levels (REP19/FH, para 56).

3. MAIN ASPECTS TO BE COVERED

- 2) Review provisions relevant to allergen labelling in the *Standard* (and related texts as required) to consider:
 - a) Scope, definitions and clarity of the existing provisions.
 - b) Presentation, legibility and the terms to be used, including the suitability of ingredient labelling provisions when making declarations.
 - c) Subject to expert advice, the list of foods and ingredients in section 4.2.1.4 (i.e. additions, deletions or exemptions) and the clarity of the groupings in that list.
- 3) Develop guidance on the use of precautionary allergen or advisory labelling including:
 - c) Principles for the use of precautionary allergen or advisory labelling.
 - d) Labelling provisions, including definition(s) for precautionary allergen or advisory labelling.
 - e) The location and appropriate Codex text(s) for the guidance.
- 4) Request scientific advice relating to the list of foods and ingredients in section 4.2.1.4 from the Joint FAO/WHO Expert Committee on Food Additives (JECFA) (and/or the WHO/FAO expert consultation that CCFH has requested be convened) on:
 - a) Whether the published criteria¹ for assessing additions and exclusions to the list is still current and appropriate.
 - b) Subject to the advice on the criteria above:
 - i) whether there are new foods and ingredients that should be added to the list.
 - ii) clarification of the groupings of foods and ingredients in the list.
 - iii) whether certain highly refined foods and ingredients can be exempted from the list.

¹ WHO Technical Report Series 896 (2000). Report of an ad hoc Panel on Food Allergens. Annex 4 of Evaluation of certain food additives and contaminants. Fifty-third report of the Joint FAO/WHO Expert Committee on Food Additives. <https://www.who.int/foodsafety/publications/jecfa-reports/en/>.

4. ASSESSMENT AGAINST THE CRITERIA FOR THE ESTABLISHMENT OF NEW WORK PRIORITIES

General criterion

Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries.

This proposed new work will review the existing provisions for the declaration of foods and ingredients known to cause hypersensitivity (allergen labelling) and develop new guidance for precautionary allergen or advisory labelling. This will provide clearer and more consistent allergen labelling information to ensure consumer protection particularly in developing countries that rely on Codex standards for their domestic situation.

Criteria applicable to general matters

a) *Diversification of national legislations and apparent resultant or potential impediments to international trade*

The proposed new work will provide greater harmonisation of allergen labelling standards at an international level. Currently there are differing national/regional standards for allergen labelling when compared to the Codex *Standard*, which is reported to impact on trade.

b) *Scope of work and establishment of priorities between the various sections of the work.*

It is proposed that a review of the *Standard* and related texts (as required) will focus on the provisions relevant to the declaration of foods and ingredients known to cause hypersensitivity (allergen labelling) and developing new guidance for the use of precautionary allergen or advisory labelling.

c) *Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies)*

This proposed new work complements and builds on work already underway by CCFH.

d) *Amenability of the subject of the proposal to standardization*

The purpose of this work is to review, update and clarify existing text and provide additional guidance to ensure a clear and contemporary set of international definitions and guidelines for allergen labelling is available for global application.

e) *Consideration of the global magnitude of the problem or issue.*

There is an increasing prevalence of food allergy occurring primarily in Western countries, such as the United Kingdom (and other countries across Europe), the United States and Australia. Elsewhere, although there is a lack of food allergy prevalence data, the data that exists indicates other countries are also experiencing an increase in the prevalence of food allergies and food allergy sensitisation. Most of these data have come from Asia (China) and Africa, although there are reports that the prevalence of food allergy is also increasing in Latin American nations.

5. RELEVANCE TO CODEX STRATEGIC OBJECTIVES

The proposed new work is in line with the Commission's mandate for the development of international standards, guidelines and other recommendations for protecting the health of consumers and ensuring fair practices in food trade. The new work proposal will contribute to advancing Strategic Goals 1, 2 and 3.

Strategic Goal 1: Establish international food standards that address current and emerging food issues

Provision of clear and consistent information is vital for food allergic consumers to make safe food choices. The review, clarification and scientific update of the existing Codex texts, in addition to developing new guidance on precautionary allergen or advisory labelling, will ensure consumer protection in the contemporary food environment.

Strategic Goal 2: Ensure the application of risk analysis principles in the development of Codex standards

The allergen labelling provisions in the *Standard*, including a list of foods and ingredients requiring declaration known to cause hypersensitivity, have not substantively changed since 1999. Therefore the proposed new work includes seeking scientific advice from FAO/WHO on the criteria for updating and clarifying this list.

Strategic Goal 3: Facilitate the effective participation of all Codex members

Consideration by CCFL will allow all Codex members the opportunity to contribute to reviewing the existing *Standard* and developing new guidance on allergen labelling. This new work complements and builds on work already underway by CCFH and provides the opportunity for cross Committee collaboration.

6. RELATION BETWEEN THE PROPOSAL AND OTHER EXISTING CODEX DOCUMENTS

The provisions relevant to allergen labelling in the *Standard* that are proposed for review are applicable horizontally across all prepackaged foods.

7. REQUIREMENT FOR AND AVAILABILITY OF EXPERT SCIENTIFIC ADVICE

Scientific advice from FAO/WHO will be needed on the criteria for any additions to and/or deletions from the list of foods and ingredients that are known to cause hypersensitivity.

8. NEED FOR TECHNICAL INPUT TO THE STANDARD FROM EXTERNAL BODIES

None identified at this stage. There will be opportunity to consult with relevant bodies if necessary throughout the process.

9. PROPOSED TIMELINE

May 2019	Agreement to new work and endorsement of new work proposal by CCFL
July 2019	Approval of new work by CAC
July 2019	Establishment of electronic working group to develop draft revised standard including new guidelines on precautionary allergen or advisory labelling
2020/21	Consideration of draft standard and scientific advice by CCFL and advancement to Step 5
2021	CAC adoption of draft standard at Step 5
2022/23	Discussion of draft standard by CCFL and advancement to Step 8
2023	CAC adoption of draft standard and guidance at Step 8